UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,980	09/10/2003	Timothy A. Hovanec	P 0284781 081289	6075

7590 01/19/2007

Pillsbury Winthrop LLP
Intellectual Property Group
Suite 2800
725 So. Figueroa Street
Los Angeles, CA 90017-5406

EXAMINER	
SALMON, KATHERINE D	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,980	HOVANEC, TIMOTHY A.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 15-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-7* is/are allowed.

6)☒ Claim(s) *15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the reply filed 11/02/2006. Currently, Claims 1-7, 15-21are pending. Claims 8-14, 22-32 have been canceled.

2. The following rejections are reiterated. Response to arguments follows.

3. This action is **FINAL**.

Withdrawn Rejections

4. The rejection made under 35 USC 112/second paragraph made in section 12 of the previous office action is moot in view of the amendment to the claims.

Reiterated Rejections

Claim Rejections - 35 USC § 112/Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting and determining the quantity of bacteria that oxidize ammonia to nitrite comprising SEQ ID No. 1 and 2 by detecting the labeled probe of SEQ ID No. 5, does not reasonably provide enablement for a method for detecting and determining the quantity of bacteria that oxidize ammonia to nitrite comprising at least 96% identity over the full length of SEQ ID No. 1 and 2 by detecting the labeled probe of SEQ ID No. 5. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claim 15 is drawn to a method for detecting and determining the quantity of bacteria that oxidize ammonia to nitrite in a medium, wherein the 16S rDNA of the bacteria includes a nucleotide sequence selected from the group consisting of a nucleotide sequences that has greater than 96% identity over the full length thereof of SEQ ID No. 1 and a nucleotide that has at least 96% identity over the full length thereof to SEQ ID No. 2 comprising a detectably labeled probe of SEQ ID No. 5, isolating DNA from the medium, exposing the isolated total DNA to the detectably labeled probe, detecting and measuring the amount of hybridized probe, wherein the presence of hybridized probe is indicative of the presence of bacteria that oxidize ammonia to nitrite and the amount of hybridized probe is indicative of the quantity of said bacteria that oxidize ammonia to nitrite in said medium. Claims 16 and 17 define the medium. Claim 18 is drawn to defining the DNA isolated from the material. Claim 19 is drawn to

providing the labeled probe on a DNA chip. Claims 20-21 define the automated process.

The claims encompass nucleic acid molecules with any number of variant positions of SEQ ID No. 1 and 2. It is unclear how much identity and which nucleotides of SEQ ID No. 1 and 2 need to be present in order to be functionally a bacteria which oxidizes ammonia to nitrite.

The claims encompass nucleic acid molecules with any number of substitutions, deletions, or insertions. The amount of sequence identity required to be a bacteria that oxidizes ammonia to nitrite is not defined in the specification. Despite knowledge in the art regarding how to mutate DNA molecules generally, the specification fails to provide guidance as to where and what type of changes in the claimed sequences will result in the retention of functional activity, reduced functional activity, or abolishment of functional activity. The breadth of these claims is much larger than the scope enabled by the specification because the claims are drawn to mutations in the sequence, which are not bound by structure or function requirements of a bacteria that oxidize ammonia to nitrite because the structure and function requirements to be considered an bacteria that oxidize ammonia to nitrite is not taught.

The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Guidance in the Specification

The specification teaches the probe comprised of SEQ ID No. 5 can detect the target groups of SEQ No. 1 and 2 (Table 10 p. 28). The specification teaches SEQ ID No. 5 targets two reactor-derived Nitrosospira-like bacteria, which are represented by the sequences of SEQ ID No. 1 and 2 to the exclusion of other beta subdivision Proteobacterial ammonia-oxidizers including the sequences represented by SEQ ID No. 3 and 4 (p. 27 lines 22-25). Therefore SEQ ID No. 5 cannot detect SEQ ID No. 3 and 4. The examiner suggests deleting SEQ ID NO. 3 and 4 from the group consisting of SEQ ID NO. 1, 2, 3, and 4 presented in Claim 1 and 15.

The specification does not make clear what percent identity SEQ ID No. 1 and 2 must have in order to be considered bacteria that oxidize ammonia to nitrite. The specification does not make clear which mutations in the 4% possible difference in SEQ ID No. 1 and 2 can be made and still retain the activity of oxidizing ammonia to nitrite. The specification does not make clear which mutations can be in the bacterial sequence and still retain the activity of oxidizing ammonia to nitrite.

The specification asserts "96% similar" means that single base substitutions may occur in up to 4% of the bases (p. 4 lines 20-21). The specification asserts a method of detecting a bacterial strain wherein the 16S rDNA of the bacteria comprises a variant of at least 96% identity to SEQ ID No. 1 and 2 (p. 14 lines 30-31 and p. 15 lines 1-5). The specification does not describe any of the possible mutants which are encompassed by the "at least 96% similar." It is unclear if a potential mutation would or would not affect the ability of bacteria to oxidize ammonia to nitrite. It is unpredictable that all possible mutations of SEQ ID No. 1 and 2 would retain function of oxidizing ammonia to nitrite.

The skilled artisan would have to perform undue experimentation to test each and every possible SNP mutation which could occur to determine the functional effect while retaining 96% structural identity.

The specification asserts variants of particular nucleotide sequences may be naturally occurring polymorphisms or synthetic sequence alterations (p. 22 lines 30-31). The specification does not provide any examples of the potential polymorphisms, which could occur in SEQ ID No. 1 and 2 and still retain 96% structural identity. The specification fails to provide any teachings of the affects of any mutations on function. It is unclear which areas of the sequence can be change and still retain the function of oxidizing ammonia to nitrite when it is unclear which parts of the sequence are critical for function. The skilled artisan would have to perform undue experimentation in order to determine which parts of the structure can be changed and still retain function.

The specification asserts hybridization may be used to detect the similarity between variant sequences and a reference sequence (p. 23 lines 6-7). The specification asserts that variants of a reference sequence can be made by using known techniques (p. 23 lines 8-9). Though, it is known in the art how to make a variant of a sequence, it is still unpredictable if a variant will retain functional activity. Without knowledge in the art or in the specification regarding the critical amino acids need to retain functionality the skilled artisan must perform undue experimentation to determine which variants retain the ability to oxidize ammonia to nitrite. It is know that 1 SNP mutation can silence the function of a gene. One SNP in the sequence of SEQ ID NO. 1 and 2 would still have the structural identity of at least 96%. It is unpredictable,

however, if sequences with at least 965% identity would retain the function to oxidize ammonia to nitrate.

Working Examples

The specification asserts amplifying rDNA SEQ ID No. 1 and 2 (p. 25 lines 1-2). The specification asserts probe (Seq ID NO. 5) detects SEQ ID No. 1 and 2 (Table 10). The specification asserts SEQ ID No. 1 and 2 represent ammonia-oxidizing bacteria Type A and subtype A1 (p. 34 lines 1-7). The specification does not teach or provide examples using sequences of less than 100% identity to SEQ ID No. 1 and 2. While the probe of SEQ ID No. 5 could detect sequences with at least 96% identity to SEQ ID NO. 1 and 2, it is unpredictable that sequences of less than 100% identity to SEQ ID No. 1 and 2 would retain the function of oxidizing ammonia to nitrite.

Although making mutations of sequences is known in the art, each mutation can have a different effect on functional activity. The specification does not teach broadly how any mutational change in SEQ ID No. 1 and 2 would affect the functionality.

The specification does not teach how much tolerance each region of the sequence has in regard to mutational changes. The specification does not support the broad scope of the claims, because the specification does not establish which regions of SEQ ID No. 1 and 2 can be modified without effecting function.

The specification does not teach all critical amino acids for retention of the functional activity of oxidizing ammonia to nitrate. The specification does not describe the structure of SEQ ID No. 1 and 2 in a way that one skilled in the art could predict the

functional effect of any SNP mutation at any position. The specification does not provide a predictable correlation between the identity or location of any of the possible mutations and the predictability of its effect on functional activity.

The unpredictability of the art and the state of the prior art

The art teaches that structure and functional relationships must be determined in order to assess how SNPs will affect activity. Tsigelny et al. (Current Medicinal Chemistry 2004 Vol 11 p. 525) teaches a method of predicting substrate binding sites (p. 525 2nd column 2nd to last paragraph). Tsigelny et al. teaches point mutations of proteins can change substrate affinity (p. 525 2nd column 2nd to last paragraph). Tsigelny et al. teaches a solved crystal structure can be used to determine if point mutations affect substrate binding (p. 525 last paragraph). Tsigelny et al. teaches modeling can be used to explain the relationship between mutations and changes in the catalytic activity of the enzyme (p. 531 1st paragraph). Tsigelny et al. teaches point mutations affecting certain motifs will affect normal function of the molecule (p. 532 1st full paragraph Gly365 to Trp and Pro379 to Leu). Tsigelny et al. teaches that based on locations of SNPs certain amino acid substitutions could be predicted to affect enzyme activity (p. 533 last full paragraph). Though Tsigelny et al. does not teach sequences involved in oxidizing ammonia to nitrite, Tsigelny et al. does show that there is a relationship between mutation and functionality. Tsigelny et al. shows that without a clear understanding of the relationship of the structure and function of a gene the effect of a mutation cannot be predicted.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters that would have to be studied. To practice the invention as broadly as it is claimed, the skilled artisan would be required to first determine which parts of the structure of SEQ ID No. 1 and 2 is critical to the function of oxidizing ammonia to nitrite.

The skilled artisan would have to take every possible mutation, which still gave at least 96% identity over SEQ ID NO 1 and 2 and determine if the mutation had any functional affect on the bacteria to oxidize ammonia to nitrite. The skilled artisan would have to mutate the sequence in every possible way and at every possible position to determine which changes to SEQ ID No. 1 and SEQ ID No. 2 could be tolerated and still retain activity. The specification and the art are silent with regard to the potential mutations in SEQ ID NO 1 and 2 at 96% identity. The art teaches that function can be affected by SNPs. The current state of the art does not support a predictable prediction of the functional effect of broadly any structural mutation.

To use the invention as presented would require a large amount of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Thus the applicants have not provided sufficient guidance to enable a skilled artisan to make the claimed invention in a manner reasonably correlated with the scope

of the claims because the scope of the claims includes any modifications of SEQ ID NO. 1 and 2 that retains at least 96% identity. These changes include unknown structural changes from any number of mutational changes. Without sufficient guidance, determination of bacteria that still retains the function of oxidizing ammonia to nitrate is unpredictable and the experimentation left to those skilled in the art is extensive.

Thus given the broad claims in an art whose nature is identified as unpredictable, the silence in the art with regard to mutational effects on the function oxidizing ammonia to nitrite, the large quantity of research required to define these unpredictable variables, and the lack of guidance provided in the specification balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

The response traverses the rejection. The response asserts the skilled artisan would be able to synthesize and identify nucleotides sequence that are variants of the reference sequence by using known techniques (p. 6 1st full paragraph). The response asserts that one of skill in the art would know which regions of the 16S rDNA gene are universally conserved between species (p. 6 last full paragraph). The response asserts that based on sequence the AOB bacteria can be distinguished from non-AOB bacteria (p. 7 1st paragraph). The response asserts the skilled artisan would recognize organism identified by SEQ ID No. 1 or 2 or variants as an AOB (p. 7 1st full paragraph). The response asserts that the examples in the specification show that the isolated and purified organism does oxidize ammonia and thus confirms this designation (p. 7 1st full

paragraph). The response asserts that AOB sequence alignment shows that only very specific regions of the bases vary (p. 7 1st full paragraph). The response asserts the hybridization language allows one skilled in the art to synthesize and identify variants of the reference sequence which share the claimed homology and also exhibit ammonia-oxidation (p. 7 last paragraph and p. 8 1st paragraph). These arguments have been fully considered but have not been found persuasive.

Though the skilled artisan could align all possible variants to SEQ ID No. 1 or 2, the skilled artisan based on the structure would not know if the variants were functionally able to oxidize ammonia. The specification does show that the isolated and purified organism of SEQ ID No. 1 and 2 does oxidize ammonia, however, the specification does not show if each potential variation of SEQ ID No. 1 or 2 which are encompassed by the claim language would have the same functionality. Therefore, the skilled artisan would have to perform undue experimentation in order to determine which of the genus of 96% equivalents were functionally able to oxidize ammonia.

The response shows that the known AOB sequences vary at specific regions. However, the specification and the art at the time of filing fails to show a predictable correlation between function and any possible variant change which could occur at 96% identity. Therefore it is unpredictable to determine which of the variants encompassed by the claim language would retain functionality.

The hybridization language amended into the claims does not remove the unpredictability of the correlation of structure and function. The variants encompassed by the claims could be 100% identical in nucleic acids to the probe of SEQ ID No. 5 (and therefore hybridize under stringent conditions) and still vary at other positions along the strand and not retain functionality.

Claim Rejections - 35 USC § 112-Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 15-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 15 is drawn to a method for detecting and determining the quantity of bacteria that oxidize ammonia to nitrite in a medium, wherein the 16S rDNA of the bacteria includes a nucleotide sequence selected from the group consisting of a nucleotide sequences that has greater than 96% identity over the full length thereof of SEQ ID No. 1 and a nucleotide that has at least 96% identity over the full length thereof to SEQ ID No. 2 comprising a detectably labeled probe of SEQ ID No. 5, isolating DNA from the medium, exposing the isolated total DNA to the detectably labeled probe, detecting and measuring the amount of hybridized probe, wherein the presence of hybridized probe is indicative of the presence of bacteria that oxidize ammonia to nitrite and the amount of hybridized probe is indicative of the quantity of said bacteria that oxidize ammonia to nitrite in said medium. Claims 16 and 17 define the medium. Claim 18 is drawn to defining the DNA isolated from the material. Claim 19 is drawn to

providing the labeled probe on a DNA chip. Claims 20-21 define the automated process.

The claims encompass nucleic acid molecules with any number of variant positions of SEQ ID No. 1 and 2. The claimed genus of "at least 96% identity" of SEQ ID NO. 1 and 2 includes mutations, which can occur at every possible nucleotide. The specification, however, fails to describe any of the possible sequence variants that can occur.

The specification does not describe detecting any bacteria with less than 100% sequence identity to SEQ ID No. 1 and 2. The specification does not teach which of the myriad of mutations that are encompassed in the genus of "at least 96%" can be used to detect bacteria that oxidize ammonia to nitrite. It is unclear in the specification if a SNP mutation in SEQ ID No. 1 and 2 would have an effect on bacteria's ability to oxidize ammonia to nitrite. The specification fails to describe mutants of SEQ ID No. 1 and 2 that retain the ability to oxidize ammonia to nitrate. The specification fails to sufficiently describe the claimed invention in clear and exact terms so that a skilled artisan would recognize that the applicants were in possession of the claimed invention at the time of filing.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The sequences encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly diverse. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments

The response traverses the rejection. The response asserts that the claims have both structural and functional limitations (p. 9 1st paragraph). The response asserts that while some of the compounds which have 96% homology might not be able to oxidize

ammonia, however, because of the requirement for maintaining a high degree of homology with SEQ ID No. 5 under specific stringent hybridization conditions have the functional requirement that oxidation of ammonia must be maintained (p. 9 1st paragraph). The response asserts that the homology and functional requirements limit the number of compounds to a defined group in which the skilled artisan would be able to identify (p. 9 2nd paragraph). These arguments have been fully considered but have not been found persuasive.

The specification has not described a large enough representation of all the variants encompassed by the claim language with regard to the effect of structure to function. It has not been described in the specification or the art at the time of filing which variants retain functionality and which do not. Further, the art teaches that even a single mutation will affect the functionality.

The hybridization language amended into the claims does not remove the unpredictability of the correlation of structure and function. The variants encompassed by the claims could be 100% identical in nucleic acids to the probe of SEQ ID No. 5 (and therefore hybridize under stringent conditions) and still vary at other positions along the strand and not retain functionality.

The response asserts that homology and functional requirements limit the number of compounds to defined group the skilled artisan would be able to identify. The specification and art at the time of filing, however, does not describe which of the variants encompassed by the claims would retain functionality. Therefore, the claims encompass variants which are not defined by the function feature of oxidizing ammonia.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Katherine Salmon
Examiner
Art Unit 1634

CARLA J. MYERS
PRIMARY EXAMINER